

Notice of Allowability

Application No.

09/866,557

Applicant(s)

HAMMOND ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/22/2005.
2. ☒ The allowed claim(s) is/are 1,9,10,12,14,15,28,47 and 48.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 8/22/05 and 2/6/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

ALLOWANCE

1. Applicant's amendment filed August 11, 2005 is acknowledged and has been entered. Claims 1 and 48 have been amended. Claims 2-8, 11, 13, 16-27 and 29-46 have been canceled. Claims 1, 9-10, 12, 14, 15, 28, 47 and 48 are currently pending. All of the amendments and arguments have been thoroughly reviewed and considered. Applicant's submission of declarations under 35 USC 1.132 and arguments place claims 1, 9-10, 12, 14, 15, 28, 47 and 48 in condition for allowance.

Declarations

2. The declarations under 37 CFR 1.132 filed August 11, 2005 are sufficient to overcome the rejection of claims 1, 9-10, 12, 14-15, 28, 47 and 48 based upon new matter under 35 USC 112 first paragraph and lack of enablement under 35 USC 112 first paragraph. Specifically, the declaration of the expert Frank Mckeeon establishes that the double stranded RNA construct of the patent application encompass hairpin RNA comprising the features claimed therein. The declaration provides evidence by explicit examples in the instant application. The declaration of the expert Gregory Hannon establishes enablement for the instant invention as claimed. The expert provides evidence in the form of post-dated publications by the Hannon lab which provides result showing the successful induction of gene silencing in cultured mammalian cells using vectors that express hairpin RNA constructs. Some of these publications include the following: Silva et al., Second-generation shRNA libraries to the mouse and human genome, unpublished manuscript; Siolas et al., Synthetic shRNA as potent RNAi triggers, Nature Biotechnology, vol. 23, no. 2, pages 227-231, 2005 and Cleary et al., Production of complex nucleic acid libraries using highly parallel in situ oligonucleotide synthesis, Nature Methods, vol.

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1, no. 3, pages 241-248, 2004. Based upon the evidence provided by the experts, the rejections noted in the prior Office action are withdrawn.

Reasons for allowance

3. The following is the examiner's reasons for allowance: The claims of the instant invention are deemed in condition for allowance based on evidence and arguments provided by Applicants in the form of a declaration under 35 USC 1.132 as discussed above. Accordingly all previous rejections have been withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

10/27/05